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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/948,149	10/09/1997	BRIAN M. FENDLY	P1053R2	6683

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/948,149

Applicant(s)

FENDLY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24November2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-40 and 42-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-40 and 42-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: copy of MTA.

DETAILED ACTION

1. Applicants' Response to Office Action, received 24 November 2004, is acknowledged.
2. Claims 28-40 and 42-64 are pending and under consideration.

Rejections Maintained

3. The rejection of claims 28-31, 37-38, 40, 56, and 57 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991) is maintained.

Applicants argue that Shepard et al fail to enable the antibodies that bind to the epitope bound by antibodies 7C2 and 7F3. Shepard et al does not identify a publically available source of antibodies that bind to the 7C2 epitope nor provides specific indications of how to obtain antibody that binds to a 7C2 epitope. Thus, Shepard et al does nothing to put one of ordinary skill in the art in possession of antibodies other than those available prior to the effective filing date of the application, such as antibody 4D5. While 4D5 is a valuable anti-erbB2 antibody, it does not bind to the 7C2 epitope, nor does Shepard et al indicate that 4D5 exhibits strong apoptotic properties, that is, induces cell death, alone.

The examiner has considered applicants' arguments, but does not find them persuasive for the reasoning put forth in all prior Office actions. Specifically, while the Material Transfer Agreement (MTA) of Genentech (attached) may contain restrictions concerning how the antibodies in question may be utilized, the MTA does not preclude anyone in the public from obtaining the antibodies if the public agrees to the conditions of the MTA. Therefore, the antibodies were available to the public at the time of the instant application. Because of this availability, a requirement for biological deposit does not apply, and the stipulations put forth in the biological deposit requirements do not apply. While Shepard et al may not specifically state

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the source of antibody, *ipsis verbis*, one of ordinary skill in the art had in their possession, at the time of the publication, the information for contacting appropriate sources, i.e., identity of the antibodies, their activity, and the address of the main author, H. Michael Shepard, Department of Biology, Genetech, Inc. 460 Point San Bruno Boulevard, South San Francisco, California 94080. Thus, Shepard et al describe the activity of the antibodies and provides a contact source for obtaining said antibodies, i.e., Shepard himself.

4. The rejection of claims 28-31, 37-38 and 40 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) is maintained.

Applicants argue that Lewis et al fail to enable the antibodies that bind to the epitope bound by antibodies 7C2 and 7F3, nor provide a publically available source of antibodies that bind to the 7C2 epitope nor provide specific indications of how to obtain antibody that binds to a 7C2 epitope. Thus, Lewis et al does nothing to put one of ordinary skill in the art in possession of antibodies other than those available prior to the effective filing date of the application, such as antibody 4D5. While 4D5 is a valuable anti-erbB2 antibody, it does not bind to the 7C2 epitope, nor does Lewis et al indicate that 4D5 exhibits strong apoptotic properties, that is, induces cell death, alone.

The examiner has considered applicants' arguments, but does not find them persuasive for the reasoning put forth in all prior Office actions. Specifically, while the Material Transfer Agreement (MTA) of Genentech may contain restrictions concerning how the antibodies in question may be utilized, the MTA does not preclude anyone in the public from obtaining the antibodies if the public agrees to the conditions of the MTA. Therefore, the antibodies were available to the public at the time of the instant application. Because of this availability, a

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requirement for biological deposit does not apply, and the stipulations put forth in the biological deposit requirements do not apply. While Lewis et al may not specifically state the source of antibody, *ipsis verbis*, one of ordinary skill in the art had in their possession, at the time of the publication, the information for contacting appropriate sources, i.e., identity of the antibodies, their activity, and the address of the main author, Gail D. Lewis, Department of Cell Analysis, Genetech, Inc. 460 Point San Bruno Boulevard, South San Francisco, California 94080. Thus, Lewis et al describe the activity of the antibodies and provides a contact source for obtaining said antibodies, i.e., Gail Lewis herself.

5. The rejection of claims 32-36, 39, and 58 under 35 U.S.C. 103(a) as being unpatentable Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), or Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993), in view of Fendly et al (*Cancer Research*, 50:1550-1558, 1990), Deshane et al (*J. Invest. Med.*, 43(Suppl 2):328A, 1995), and further in view of Senter et al (U.S. Pat. No. 4,975,278) is maintained.

Applicants concerning Shepard et al and Lewis et al are identical to those put forth *supra*. Applicants arguments concerning Fendly et al are identical to the arguments concerning Shepard et al and Lewis et al.

The examiner has considered applicants' argument, but does not find it persuasive for the reasoning put forth in the original rejection as well as the discussion of Shepard et al, and Lewis et al, *supra*.

Applicants did not put forth arguments concerning Deshane et al nor Senter et al.

6. The rejection of claims 42-55 and 59-62 under 35 U.S.C. 103(a) as being unpatentable Shepard et al (*J. Clinb. Immunol.*, 11(3):117-127, 1991), in view of Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) and Fendly et al (*Cancer Research*, 50:1550-1558,

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1990), and further in view of Deshane et al (*J. Invest. Med.*, 43(Suppl 2):328A, 1995) and Senter et al (U.S. Pat. No. 4,975,278) is maintained.

Applicants concerning Shepard et al and Lewis et al are identical to those put forth *supra*. Applicants arguments concerning Fendly et al are identical to the arguments concerning Shepard et al and Lewis et al.

The examiner has considered applicants' argument, but does not find it persuasive for the reasoning put forth in the original rejection as well as the discussion of Shepard et al, and Lewis et al, *supra*.

Applicants did not put forth arguments concerning Deshane et al nor Senter et al.

7. The rejection of claim 63 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991) is maintained.

Applicants argue that Shepard et al does not show that 4D5, as an isolated antibody kills any cell and that the claims are not satisfied unless the antibody, alone, induces cell death.

The examiner has considered applicants arguments, but does not find it persuasive for the reasons put forth in the original rejection. Because Brian M. Fendly is both a coauthor of the reference and co-inventor of the instant application, the antibody, 4D5 in the reference is the same antibody 4D5 of the instant application, thus exhibits the same characteristics. No evidence to the contrary has been put forth by applicants to show that the identity of 4D5 in the two instances are different.

For availability of the antibody to the public, see the above discussion of Shepard et al and Material Transfer Agreement of Genentech.

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8. The rejection of claim 63 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) is maintained.

Applicants argue that Lewis et al, as pertains to Shepard et al, *supra*, does not provide public availability of the necessary antibody, nor show the required activity of the antibody in question.

The examiner has considered applicants' argument, but does not find it persuasive. As stated in the original rejection, Lewis et al do teach the required antibody, 4D5 and Brian M. Fendly is both a coauthor of the reference and co-inventor of the instant application, the antibody, 4D5 in the reference is the same antibody 4D5 of the instant application, thus exhibits the same characteristics. No evidence to the contrary has been put forth by applicants to show that the identity of 4D5 in the two instances are different.

9. The rejection of claim 64 under 35 U.S.C. 103(a) as being unpatentable over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), or Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993), in view of Fendly et al (*Cancer Research*, 50:1550-1558, 1990) is maintained.

Applicants concerning Shepard et al and Lewis et al are identical to those put forth *supra*. Applicants arguments concerning Fendly et al are identical to the arguments concerning Shepard et al and Lewis et al.

The examiner has considered applicants' argument, but does not find it persuasive for the reasoning put forth in the original rejection as well as the discussion of Shepard et al, and Lewis et al, *supra*.

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10. The rejection of claim 64 under 35 U.S.C. 112, second paragraph, lack of antecedent basis for the limitation "the method of claim 63 wherein said second anti-ErbB2 antibody" in line 1, is maintained for reasons put forth in the original rejection.

Applicants remarks do not address this rejection.

Conclusion

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

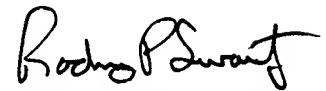
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

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The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

March 1, 2005